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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,441	09/08/1999	Christen M. Anderson	660088.420C1	2716

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/02/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/393,441

Applicant(s)

ANDERSON ET AL.

Examiner

Sheridan K Snedden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 21, 2002, Paper No. 15.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52, 53 and 56 are cancelled; claims 42, 46-48, 51, and 57 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42, 46-48, 51 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

33DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper #15, filed August 21, 2002. Claims 52-53 and 56 have been canceled. Applicant's amendment of claims 42, 46, 47, 51 and 57 is acknowledged. Claims 42, 46-48, 51 and 57 are under examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawal of Objections and Rejections

3. The objections and/or rejections not explicitly restated or stated below are withdrawn.
4. The rejection of claim 42, 47, 48 and 51 under USC 112, first paragraph, is withdrawn as the claim recites a specific ANT protein, ANT3.
5. The rejection of claim 46 under USC 112, first paragraph, is withdrawn as the claim has been amended to remove the "variant of fragment" thereof language.
6. All rejection under USC 102(a) and USC 103(a) are withdrawn as the claims have been amended to recite a protein with 95% identity to ANT3.

Maintained Rejections

Double Patenting

7. Claims 42, 46-48, 51 and 57 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 42, 46-48, 51 and 57 of copending Application No. 09/185,904. This is a provisional double patenting rejection since the conflicting claims have not

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in fact been patented. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

8. The claims as amended of copending Application No. 09/185,904 are identical to the amended claims in the present application. The rejection is maintained.

New Rejections

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42, 47, 51 and dependent claims thereto are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 47 and 51 recite the limitation "wherein the ANT polypeptide comprises an amino acid sequence that is at least 95 percent...". There is insufficient antecedent basis for ANT in this limitation in the claim (see also ANT ligand). Additionally, the acronym 'ANT' should be spelled out in all independent claims (see also claim 42).

Claim Rejections - 35 USC § 102

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10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42 and 46 rejected under 35 U.S.C. 102(b) as being anticipated by Cozens *et al.*

(J Mol Biol. 1989 Mar 20;206(2):261-80). Cozens *et al.* teach a human mitochondrial ADP/ATP translocase protein, or ANT protein, that is 100% identical to the amino acid sequence of SEQ ID NO:33 (regarding claim 42). The protein taught by Cozens *et al.* is a mitochondrial ATP/ADP carrier and thus localizes to the mitochondria and binds to ANT ligand (addressing limitations of claim 42). Further limitations of the claim 42 and claim 46 are concerned with the production of the protein, and thus, claim a product-by process (the reference meets the claim limitation of not having endogenous human ANT1 because it is an *E. coli* cell). Cozens *et al.* does not teach the process of producing ANT3 protein by recombinant expression. However, Applicant is reminded of the following excerpt: “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

“The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature” than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326

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(CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In *re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). Thus, absent a factual statement to the contrary, the reference anticipates the claimed product of the invention.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42, 46, 47, 48, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cozens *et al.* (J Mol Biol. 1989 Mar 20;206(2):261-80) in view of Adrian *et al.* (Mol Cell Biol (1986)6(2): 626-634) and Rosenberg (ref CE of IDS).

Cozens *et al.* teach a human mitochondrial ADP/ATP translocase protein, or ANT protein, that is 100% identical to the amino acid sequence of SEQ ID NO:33 (regarding claim 42). The protein taught by Cozens *et al.* is a mitochondrial ATP/ADP carrier and thus localizes to the mitochondria and binds to ANT ligand (addressing limitations of claim 42).

Cozens *et al.* does not teach the process of producing ANT3 protein by recombinant expression (claims 42 and 46) and does not teach an ANT fusion protein (claims 47, 48, 51 and 57).

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Adrian *et al.* teach an ANT protein fused to the enzyme beta-galactosidase, which binds to the ligand lactose (regarding claims 47, 48 and 57). Adrian *et al.* recombinantly expresses the ANT protein in the host cell *S. cerevisiae* using an expression construct comprising a promoter operably linked to the nucleic acid encoding the ANT polypeptide (see Methods and Materials; regarding claim 42). The yeast host cell would not express endogenous human ANT1 or human ANT2 (regarding claim 46). Adrian *et al.* do not teach a human ANT3 protein or a fusion protein in which a protease would separate the ANT3 protein and beta-galactosidase.

Rosenburg teaches that is standard in the art to construct fusion proteins between a protein of interest and an enzyme (for example β -galactosidase or β -Gal, see pages 336, lines 3-6 and the section titled "Expression and Purification of lacZ and trpE fusion proteins"). Rosenburg teaches that using β -Gal can be used as a fusion partner to provide an advantage because antibodies to β -Gal can be used to affinity purify the fusion protein. Rosenburg teaches that a protease cleavage site can easily be engineered into the fusion so that the fusion partner can be separated from the protein of interest after purification (see page 344, section 11.15, regarding claim 51).

Taken together, the above references teach a human ANT3 polypeptide 100% identical to the sequence set forth as SEQ ID NO: 33, a fusion protein of the above sequence with the enzyme β -Gal, in which β -Gal is capable of binding to lactose or an antibody and where the protein is engineered in a manner so that a protease may be used to separate the above fusion partners. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to substitute the human ANT protein taught by Cozens *et al.* for the yeast ANT protein taught by Adrian *et al.* to obtain the fusion protein. It would have been obvious to

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the person of ordinary skill in the art at the time the invention was made to engineer a protease cleavage site within the protein fusion construct as taught by Rosenberg. The person of ordinary skill in the art would have been motivated to make the above modifications in order to facilitate the recombinant production and purification of the protein of the protein taught by Cozens *et al.* with the methods taught by Rosenberg. The person of ordinary skill in the art would have expected results because the preparation of fusion proteins with β -Gal and the incorporation of a protease cleavage site are standard methods in the art for the study, recombinant production and rapid purification of protein, and in the case of Adrian *et al.*, have been demonstrated with ANT proteins. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

11. No Claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843.

The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

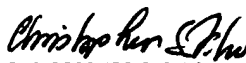
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3975 for regular communications and (703) 746-3975 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS

November 27, 2002

SKS


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800